ode: 4150-36

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS

**ACTION**: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES**: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 264-0041, or PRA@HHS.GOV. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Research Complaint Form

Type of Collection: New

OMB No. 0990-new

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is requesting a new approval from the Office of Management and Budget of OHRP's Research Complaint Form. This form will provide a simplified standardized format for submitting to OHRP allegations of noncompliance involving human subject research conducted or supported by HHS, which should significantly improve OHRP's capacity to review and process these allegations. The information collected will help OHRP ensure the rights of human subjects involved in such research and that OHRP-assured institutions are complying with the HHS Protection of Human Subjects regulations.

Type of Respondent: IRB members, IRB Administrators, Research Coordinators, and the Public. Estimated Annualized Burden Table

| Type of<br>Respondent  | No. of<br>Respondents | No.<br>Responses<br>per<br>Respondent | Average Burden<br>per Response (in<br>hours) | Total Burden Hours |
|--|-----------------------|---------------------------------------|--|--------------------|
| IRB members, IRB Administrators, Research Coordinators, the Public | 500                   | 1                                     | 30/60  | 250                |
| IRB members, IRB Administrators, Research Coordinators, the Public | 400                   | 2                                     | 30/60  | 400                |
| IRB members, IRB Administrators, Research Coordinators, the Public | 100                   | 3                                     | 30/60  | 150                |
| Total  |                       |                                       |  | 800                |

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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